

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gopi M. Venkatesh et al.

Application No.: 10/827,106

Confirmation No.: 1448

Filed: April 19, 2004

Group Art Unit: 1618

For: ORALLY DISINTEGRATING TABLETS
AND METHODS OF MANUFACTURE

Examiner: SAMALA, Jagadishwar
Rao

PRE-APPEAL BRIEF REQUEST FOR REVIEW

U.S. Patent and Trademark Office
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Sir:

In response to the FINAL Office Action issued June 22, 2007, Applicants submit herewith the following Pre-Appeal Brief Request for Review and a Notice of Appeal.

Remarks begin at page 2 of this paper.

REMARKS

Applicants respectfully submit that Claims 1-24 have been improperly rejected because the Examiner has failed to adequately support both a *prima facie* case of anticipation and obviousness.

In the Final Office Action issued June 22, 2006 the Examiner rejected claims 1-24 under 35 U.S.C. §102(b) over *Ohta* (EP 0914818 A1). Furthermore, the Examiner rejected claims 1, 11, and 12 under 35 U.S.C. §103(a) over the combination of *Ohta* and *Cherukuri* (US 2002/0044962), and claims 1-24 over the combination of *Percel* (US 6451345) and *Masaki* (US 5466464).

I. Rejection under 35 U.S.C. § 102(b)

Applicants respectfully submit that *Ohta* does not support a *prima facie* case of anticipation for at least the following reasons:

Ohta does not teach each and every limitation set forth in claim 1, either expressly or inherently in its disclosure. Specifically, *Ohta* does not teach “microencapsulating” milled granules, and thus does not describe granules having a microencapsulation coating.

Further, *Ohta* does not teach a compressed blend of two types of particles, namely (a) “rapidly dispersing microgranules” and (b) “taste-masked microcapsules”. (see Applicants’ Amendment under 37 C.F.R. §1.116 filed September 24, 2007 [hereinafter “Applicants’ Amendment”], Section II).

A. Each and Every Limitation in Claim 1 is Not Taught, Either Expressly or Inherently.

The Examiner states that *Ohta* “meets the structural limitations of the instant claims” even though *Ohta* “does not explicitly teach about a taste-masked microcapsule”.¹

As discussed at pages 8-9 of Applicants’ Amendment, the claimed invention comprises a combination of rapidly dispersing microgranules and taste-masked microcapsules, wherein the taste-masked microcapsules are prepared by microencapsulating drug-containing milled

¹ Final Office Action, dated June 22, 2007, at page 3, lines 7-8

granules. Thus, the tablets of the claimed invention have two types of particles, and the taste-masked microcapsules have the structure of drug-containing granules microencapsulated with a coating. In direct contrast, the tablets of *Ohta* contain only a single type of particle, i.e. obtained upon granulating a single mixture of sugar alcohol, an “active ingredient”, a disintegrant, and optionally a binder. Further, the tablets of *Ohta* contain uncoated drug crystals, and therefore lack a coating corresponding to the coating of the “taste-masked microcapsules” of the claimed invention. Thus, *Ohta* does not expressly anticipate the structural characteristics of the claimed invention.

Furthermore, since the structure of the claimed tablets differs significantly from the tablets of *Ohta* (see above), the tablets of *Ohta* would reasonably have a different dissolution profile, and hence cannot reasonably inherently disclose the dissolution profile limitation of the claimed tablets.

II. Rejection under 35 U.S.C. § 103(a)

Applicants respectfully submit that neither the combination of *Ohta* and *Cherukuri*, nor the combination of *Percel* and *Masaki* support a *prima facie* case of obviousness. Both combinations of references fail to teach all of the limitations of the claimed invention.

Furthermore, Applicants submit that there is no reasonable motivation to combine *Ohta* and *Cherukuri*.

A. *Ohta* and *Cherukuri* Do Not Suggest or Teach “Taste-Masked Microgranules” and a Compressed Blend of Two Type of Particles

As discussed above, the tablets of *Ohta* comprise a single type of granule and do not include taste-masked microgranules comprising an encapsulation coating over drug-containing particles. *Cherukuri* does not remedy these deficiencies of *Ohta* because the tablets of *Cherukuri* also comprise a single type of granule, and provide for a coating on the *entire tablet* (rather than on the drug-containing granules within the tablet, as in the claimed invention). (see Applicants’ Amendment, Section (III)(A), pages 10-11). Thus, the combination of *Ohta* and *Cherukuri* does not teach or suggest all of the limitations of the claimed invention.

B. *Percel* and *Masaki* Do Not Suggest or Teach the Claimed “Rapidly Dispersing Granules”, a “Polymeric Binder” And a Compressed Blend of Two Type of Particles

The Examiner states that *Percel* in combination with *Masaki* provide [the] desired dissolution and taste-masking formulations in the form [of] tablets along with similar binders and other common excipients” (Final Office Action, dated June 22, 2007, at page 5, lines 16-22).

As discussed at pages 12-13 of Applicants’ Amendment, *Percel* describes compositions comprising encapsulated drug-crystals. However, the claimed “taste-masked microcapsules” comprise “at least one drug” and “at least one polymeric binder” (emphasis added). Thus, the drug-containing particles of *Percel* lack the “at least one polymeric binder” limitation of the claimed tablets.

In addition, the compositions of *Percel* are prepared by simply combining all of the ingredients prior to compression, and thus do not describe a discrete “rapidly dispersing microgranule” (i.e., comprising a sugar alcohol or saccharide and a disintegrant having an average particle size of less than 30 microns) as in the claimed invention. Thus, the compositions of *Percel* are quite different from the compositions of the claimed invention.

Furthermore, *Masaki* does not remedy these deficiencies of *Percel*. The tablets of *Masaki* also do not include taste-masked particles comprising a microencapsulated drug/binder, rapidly dispersing microgranules comprising a sugar alcohol and disintegrant, or tablets comprising a compressed blend of taste-masked microcapsules and rapidly dispersing microgranules. Thus, the combination of *Percel* and *Masaki* do not teach either the microencapsulated drug/binder-containing particles or the rapidly dispersing microgranules of the claimed invention.

C. No motivation to combine *Ohta* and *Cherukuri*

As discussed at pages 10-11 of Applicants’ Amendment, and above in section I of this Pre-Appeal Brief Request for Review, Applicants note that the tablets of *Ohta* are orally disintegrating² and thus inherently have immediate release properties (i.e., because the drug-containing granules are uncoated). *Cherukuri*, in contrast, describes tablets or caplets intended to be swallowed whole for absorption in the lower GI tract, and are clearly not intended as

² *Ohta*, ¶ [0003]

immediate release formulations because they are coated with controlled or extended release coatings (which are designed to impede release of the drug). Because the compositions of *Ohta* and *Cherukuri* are so different, there is no reasonable suggestion or motivation to combine their teachings because doing so would reasonably render the dosage forms of either reference unsuitable for their intended use, and/or change their respective principles of operation (see MPEP 2143.01 (V) & (VI)).

For the reasons stated above, Applicants respectfully submit that the claims are in condition for allowance, early notice of which would be appreciated.

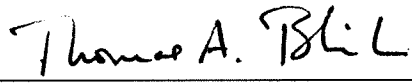
Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.136(a)(3).

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